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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,037	07/24/2001	Ben M. Dunn	UF-219XC1	2654

7590 10/02/2002

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/02/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/763,037	DUNN ET AL.
	Examiner	Art Unit
	Cybille Delacroix-Muirheid	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 October 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5-9 and 12-15 is/are rejected.
- 7) Claim(s) 3,4,10 and 11 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

The following is responsive to the preliminary amendment received Oct. 11, 2001.

No claims are cancelled. No new claims are added.

Claims 1-15 are presented for prosecution on the merits.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Dec. 3, 2001 has been considered.

Please refer to Applicant's copy of the 1449 submitted herewith.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2, 5-9, are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/22778 ('778) and Hart et al. and Budt et al. (Abstract) in view of Torres and Johnson et al. WO '778 disclose methods for treating FIV using the disclosed nucleoside analogues. Please see the abstract; pages 8, lines 1-3.

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Hart et al. teach methods for treating FIV infected cats by oral administering to the cats effective amounts of AZT. Treatment lead to total recovery from clinical symptoms in six of the nine FIV-infected cats. Please see the abstract.

Budt et al. disclose that the compound HBY-793 is a known HIV protease inhibitor. Please the abstract submitted herewith.

WO '778 and Hart et al. and Budt et al. do not disclose treating FIV infected cats with a combination of AZT, a nucleoside analogue such as 3TC and a protease inhibitor (such as HBY-793); however, the Examiner refers to (1) Torres, which discloses compositions for use in anti-HIV therapy wherein the compositions contain three anti-HIV drugs . Specifically, Torres et al. teach that the compositions may comprise (1) AZT +(2) 3TC + (3) saquinavir (SQV, protease inhibitor) or (1) AZT + (2) 3TC +(3) ritonavir (RTV, protease inhibitor). Please see page 157, Table VII , page 158; and (2) Johnson et al., which disclose that FIV closely resembles HIV in genomic organization, protein composition and morphology (see page 225, first column , beginning of second paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of WO '778, Hart and Budt et al. to include administration of combination comprising AZT; 3TC and protease inhibitors such as saquinavir or ritonavir or HBY-793 or AZT and 3TC because Torres discloses that combination therapy may provide synergistic or additive effects against HIV and may further prevent or delay resistance to the drugs. Furthermore, since Johnson discloses that FIV is similar to HIV, one of

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ordinary skill in the art would reasonably expect the anti-HIV combinations disclosed in the prior art to be effective against FIV in felines. Such a modification would have been motivated by the reasoned expectation of producing a combination composition which would effectively treat FIV in cats. Finally, it would have been obvious to one of ordinary skill in the art to provide additional protease inhibitors such as HBY-793 with the reasonable expectation that HBY-793 in combination with the AZT and nucleoside analogue or AZT ,nucleoside analog and protease inhibitor would provide effective anti-viral therapy.

5. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torres et al. in view of Budt et al. (Abstract)

Torres et al. disclose compositions for use in anti-HIV therapy wherein the compositions contain three anti-HIV drugs . Specifically, Torres et al. teach that the compositions may comprise (1) AZT +(2) 3TC + (3) saquinavir (SQV, protease inhibitor) or (1) AZT + (2) 3TC +(3) ritonavir (RTV, protease inhibitor). Please see page 157, Table VII , page 158.

Torres does not disclose combining the protease inhibitor HBY-793, yet the Examiner refers to Budt et al., which disclose that HBY-793 is a known HIV protease inhibitor. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the combination compositions of Torres by adding protease inhibitors such as HBY-793 with the reasonable expectation that HBY-793 in combination with the AZT, nucleoside analogue and protease inhibitor would provide effective anti-viral therapy.

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Torres does not specifically disclose a "kit" containing such a combination composition; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of Torres into a kit because one of ordinary skill in the art would reasonably expect the composition provided in kit form to be readily available to a patient in need thereof. Moreover, modification of the compositions of Torres into a kit containing one or more containers would have been obvious and well within the capability of the skilled artisan.

Allowable Subject Matter

6. Claims 3, 4, 10, 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-2, 5-9, 12-15 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



Oct. 1, 2002



Cybille Delacroix-Muirheid
Patent Examiner Group 1600